

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE: NEW ENGLAND COMPOUNDING
PHARMACY, INC. PRODUCTS LIABILITY
LITIGATION

MDL No. 1:13-md-2419-RWZ

THIS DOCUMENT RELATES TO:

Montee v. New England Compounding Pharmacy, Inc., et al.
Docket No. 13-cv-12657;
Cooper v. New England Compounding Pharmacy, Inc., et al.
Docket No. 13-cv-12658; and
Cooper v. New England Compounding Pharmacy, Inc., et al.
Docket No. 13-cv-12659.

**PLAINTIFFS' STEERING COMMITTEE'S MEMORANDUM OF LAW IN
OPPOSITION TO BKC DEFENDANTS' MOTION TO DISMISS PURSUANT TO
F.R.C.P. 12(b)(6).**

INTRODUCTION

It is undisputed that the widespread outbreak of fungal meningitis, which gave rise to this multi-district litigation, was caused by contaminated preservative free methylprednisolone acetate (“MPA”) compounded by New England Compounding Center, Inc. (“NECC”) being administered to patients at over 70 pain clinics, orthopedic practices and hospitals,¹ including the BKC Defendants.² Liability extends to the health care providers and facilities that purchased the contaminated product and distributed it to their patients. Despite extensive guidelines setting forth doctors and clinics responsibilities when outsourcing risky compounded drugs, the BKC Defendants failed to perform any due diligence. Instead, the BKC Defendants mail ordered hundreds of vials of prescription preservative free MPA from NECC without any reasonable effort to assess and evaluate NECC’s ability to aseptically make, package and dispense preservative free MPA.

The Master Complaint³, filed by the Plaintiffs’ Steering Committee on November 5, 2013 and incorporated by reference through the filing of the Short Form Complaints in the above-captioned related actions by the responding Plaintiffs, sets forth in great detail the reasons why these healthcare providers, including the BKC Defendants, share responsibility for Plaintiffs’ injuries and harm. Without BKC’s negligent and reckless conduct in mail ordering and purchasing contaminated steroids and administering them to patients without performing any due diligence the Plaintiffs would not have received contaminated MPA in their spinal column

¹ See CDC, Multistate Fungal Meningitis Outbreak Investigation, <http://www.cdc.gov/hai/outbreaks/meningitis-map-large.html> (Visited March 2014); see also FDA, Multistate outbreak of fungal meningitis and other infections, <http://www.fda.gov/%20Drugs/DrugSafety/FungalMeningitis/default.htm>; Smith, Rachel M., et al., *Fungal Infections Associated with Contaminated Methylprednisolone Injections*, N Engl J Med 2013; 369:1598-1609 (Oct. 24, 2013).

² “BKC Defendants,” “Defendants” and/or “BKC” refers collectively to Defendants BKC Pain Specialists, LLC, Nikesh Batra, M.D., and Adil Katabay, M.D.

³ Master Complaint against UniFirst and Clinic-Related Defendants, Dkt. No. 545, as amended by Dkt. No. 832, hereinafter “Master Complaint” or “Complaint.”

causing them to suffer serious injuries. The factual and legal allegations in the Master Complaint concerning the “Clinic Related Defendants”⁴ are thorough, well-pleaded, and sufficiently state claims upon which relief can be granted. Plaintiffs plead an actionable multi-count case that the BKC Defendants without due, proper and necessary qualification of NECC’s competence and ability acquired and administered adulterated preservative free MPA from NECC, and, importantly, did so by submitting prescriptions to NECC that flagrantly violated Massachusetts’ controlled substances law⁵, Massachusetts’ consumer protection law⁶, Ohio Products Liability Law⁷, and Ohio’s Consumer Protection Laws⁸.

The Master Complaint is lengthy and describes in a detailed manner how the BKC Defendants’ conduct contributed to the outbreak. For example, the Complaint alleges that Defendants failed to exercise reasonable care to ensure that the drugs they purchased and administered to Plaintiffs were manufactured in compliance with applicable pharmaceutical laws. Master Compl., ¶ 234(a). The Complaint alleges that the BKC Defendants failed to perform the necessary due diligence to determine the safety and quality of NECC’s drugs and failed to determine if NECC could properly provide sterile, preservative free drugs for administration to patients. Master Compl., ¶ 234(d). The Complaint also states that the BKC Defendants failed to conduct sufficient due diligence to determine whether NECC was a reputable and safe supplier of sterile injectable compounds and the Complaint asserts that BKC

⁴ The Master Complaint lists a number of facilities that received recalled lots of MPA from NECC. Those hospitals, clinics, healthcare facilities, and their physicians, staff, agents, and employees are referred to in the Master Complaint collectively as the “Clinic Related Defendants.” Master Compl. ¶¶ 22-23. The BKC Defendants are included in this defined term. *Id.* at 22. In addition, because the Master Complaint was adopted and incorporated by reference in each of the above-captioned related actions, the term “Clinic Related Defendants” has come to include and apply to the BKC Defendants.

⁵ MGL Ch. 94C §1 et seq.

⁶ MGL Ch. 93A.

⁷ Ohio Products Liability Act.

⁸ Ohio Admin. Code 4729-5-30(B) (requiring a prescription to contain the patients full name and residential address).

purchased compounded drugs in bulk from NECC without using patient specific individual prescriptions as required by law. Master Compl., ¶ 234(j)(q). In addition, the Master Complaint avers that as a result of BKC's conduct, Plaintiffs were administered contaminated products causing serious injuries and, in some cases, death. Master Compl., ¶¶ 270, 271, 298, 303, 355.

The Master Complaint and the Short Form Complaints (by adoption and incorporation by reference) set forth the following causes of action against the BKC Defendants: Count III – Negligence and Gross Negligence; Count IV – Violation of the Ohio Consumer Protection Statute (O.R.C. §§ 1345.01 et seq. and O.A.C. §§ 109:4-3-01 et seq.); Count VII – Battery; Count VIII – Failure to Warn; Count IX – Ohio Product Liability Claims; Count X – Agency; Count XI – Civil Conspiracy; Count XIII – Loss of Consortium; and Count XIV – Punitive Damages.

The BKC Defendants filed the instant Rule 12(b)(6) Motion to Dismiss seeking dismissal of each cause of action. However, for the reasons below, Plaintiffs have more than adequately stated their claims and BKC Defendants' Motion to Dismiss should be denied.

STANDARD OF REVIEW

In deciding a motion to dismiss, “a court does not rule on the evidentiary sufficiency of a complaint, only on whether its factual and legal assertions allege ‘a plausible entitlement to relief.’” *Balerna v. Gilberti*, CIV.A. 09-10075-RGS, 2010 WL 4878286, at *4 (D. Mass. Nov. 24, 2010); (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 559 (2007)). In considering a motion to dismiss, the court should “treat as true all well-pleaded facts, viewing those facts in the light most favorable to the plaintiff, and drawing all reasonable inferences therefrom for [plaintiff].” *Knowlton v. Shaw*, 704 F.3d 1, 3 (1st Cir. 2013) (citing *Gagliardi v. Sullivan*, 513 F.3d 301, 305 (1st Cir.2008)). Under *Twombly*, a complaint need only allege “enough factual

matter (taken as true) to suggest” the validity of the claim. *Twombly*, 550 U.S. at 557. “To justify a dismissal on any Civ. R. 12(B)(6) motion, the court must find beyond doubt from the complaint that the plaintiffs can prove no set of facts entitling them to relief.” *Saylor v. Providence Hosp.*, 113 Ohio App. 3d 1, 3-4, 680 N.E.2d 193, 194-95 (1996).

LAW AND ARGUMENT

I. Plaintiffs Reserve the Right to Argue Massachusetts Law Rather than Ohio Law Should Be Applied to the Instant Case

Plaintiffs do not concede that Ohio substantive law is applicable in the instant case, and importantly, the BKC Defendants fail to make any choice of law analysis whatsoever to support their contention that Ohio law applies to Plaintiffs’ claims.⁹ In raising this issue, Plaintiffs reserve the right to fully brief the choice of law analysis at a later date. In sum, Plaintiffs will argue that the Commonwealth of Massachusetts has a significant interest in the litigation so as to make the application of Massachusetts substantive law appropriate. Plaintiffs contend that Massachusetts has a more significant interest than Ohio because the majority of the wrongful conduct, at the heart of this litigation, took place in Massachusetts. For example: the compounding facility at the source of this litigation was located in Massachusetts, the methylprednisolone acetate was actually compounded in Massachusetts, the contamination took place in Massachusetts, Defendants intentionally placed bulk orders to the facility they knew was regulated by the laws of Massachusetts not the FDA, Defendants had the drugs shipped from Massachusetts, Defendants paid for the contaminated MPA and payment was processed in Massachusetts and Defendants did nothing to verify or investigate the safety measures taken by the facility. Consequently, since the majority of the wrongful conduct took place in

⁹ In their Motion to Dismiss, Defendants present no support for their contention that Ohio law will be applicable, rather than Massachusetts substantive law.

Massachusetts, this court should apply Massachusetts substantive law to the instant case.¹⁰

Nonetheless, Plaintiffs' complaints meet the pleading requirements of both Massachusetts and Ohio law and Plaintiffs address Ohio law herein in response to BKC's motion.

II. Plaintiff Brandy Cooper Received Injections of NECC's Contaminated MPA as Memorialized by BKC Defendants' Own Documents.

Despite the BKC Defendants' disingenuous argument otherwise, their own documents establish that Plaintiff Brandy Cooper did receive NECC's contaminated MPA. Indeed, BKC Defendants' response to the Court's order to produce a list of patients who were administered MPA from one of the three contaminated lots specifically included Plaintiff Brandy Cooper (and Pamela Cooper and Donna Montee). *See Exhibit 1*. The chart produced by BKC Defendants in August, 2013, clearly corroborates the allegations Plaintiff Brandy Cooper made in her Short Form Complaint stating she received a contaminated injection of the preservative free MPA from Dr. Katabay on May 30, 2012. *See B. Cooper Short Form Compl.*, Dkt. No. 1:13-cv-12658-RWZ, Doc. No. 23, filed December 19, 2013.

In addition, medical records produced by the BKC Defendants further substantiate that

¹⁰ *Boston Hides & Furs, Ltd. v. Sumitomo Bank, Ltd.*, 870 F. Supp. 1153, 1166-67 (D. Mass. 1994) (In analyzing a choice of law issue, "[Massachusetts] courts preferred either a "place of conduct" analysis, focusing on the location of the alleged conduct which violated Chapter 93A (internal citation omitted) or a "functional approach" which "responds to the statutory concern with commercial conduct in Massachusetts."); *Auto Europe, LLC v. Connecticut Indem. Co.*, 321 F.3d 60, 66 (1st Cir. 2003) (Illinois plaintiffs filed a consumer fraud suit against an automobile insurance company and that company's insurer refused to defend it in the pending suit. The court held that even though plaintiffs were located in Illinois and the insurer was located in Florida, Maine law was applicable because the insured was located in Maine and the underlying lawsuit was based on wrongful conduct allegedly committed in Maine.); *Tingley Sys., Inc. v. CSC Consulting, Inc.*, 152 F. Supp. 2d 95, 115 (D. Mass. 2001) (In a misappropriation of trade secret claim, the court found the place of injury did not play an important role and, "Instead, the principal location of the defendant's conduct is the contact that will usually be given the greatest weight in determining the state whose local law determines the rights and liabilities that arise from...the misappropriation of trade values." *Id.* quoting *Restatement (Second) of Conflict of Laws*, § 145, Comment (f) (1971).); *See also Data Cash Systems, Inc. v. JS & A Group, Inc.*, 480 F.Supp. 1063, 1071 (N.D.Ill.1979), *aff'd*, 628 F.2d 1038 (7th Cir.1980) ("...principal location of the defendant's conduct is the contact that is usually given the greatest weight in determining" the choice of law in an unfair competition claim).

Plaintiff Brandy Cooper received NECC's contaminated MPA. Indeed, one of the medical records dated October 17, 2012 reads, in pertinent part, "The pt was notified of the symptoms of fungal meningitis and asked if they have had or if they are experiencing any of these symptoms...The pt was notified to seek immediate medical attention at the ER or urgent care if they have or if they develop any of these sxs. Pt was + for HA, nausea, stiff neck. Pt was advised to go to the ER to be evaluated for fungal meningitis." *See Exhibit 2.* This communication note clearly shows the BKC Defendants concern and conviction that Plaintiff Brandy Cooper was infected by one of the contaminated lots of MPA, advising her to seek immediate treatment. Moreover, Plaintiff Brandy Cooper sets forth allegations substantiated by this record in her Amended Complaint, specifically, that she was contacted by someone at BKC pain specialists and told to report to the emergency room to be evaluated for fungal meningitis. *See B. Cooper Amended Short Form Compl., Dkt. No. 1:13-cv-12658-RWZ, Doc. No. 23, filed December 19, 2013.*

It is not until now, when the BKC Defendants' have been sued, that they change their position and insincerely claim that Plaintiff Brandy Cooper did not receive contaminated MPA. Indeed, the sole information relied upon to make this assertion is the statement of a named Defendant, Dr. Katabay, who certainly now has an interest in disclaiming any injury and liability. BKC Defendants' late distortion of the facts is not sufficient to warrant dismissal. Furthermore, BKC Defendants' ignore entirely that all allegations are to be taken in the light most favorable to the Plaintiff Brandy Cooper. Because Plaintiff Brandy Cooper has sufficiently pled allegations in her Amended Complaint stating a plausible right to relief, BKC Defendants' motion must be denied.

III. Plaintiffs' Complaints Sufficiently Allege Negligence and Gross Negligence

A. Plaintiffs Adequately Plead Duty

The BKC Defendants cannot deny that they owed a duty to exercise reasonable care when treating Plaintiffs. This is precisely what the Plaintiffs have sufficiently pled. Master Compl., ¶¶ 152, 227-231. And while Plaintiffs allege, in part, that the exercise of due care requires that the BKC Defendants perform some level of due diligence prior to injecting them with a dangerous drug that was compounded, not FDA approved, into their vulnerable spinal column, such allegations are not a “drastic expansion of existing law.” Indeed, a case cited by the Defendants themselves, sets forth that “any number of considerations may justify the imposition of duty in particular circumstances, including the guidance of history, our continually refined concepts of morals and justice, the convenience of the rule, and social judgment as to where the loss should fall.” *Musivand v. David*, 45 Ohio St.3d 314, 318, 544 N.E.2d 265, 269–270 (1989). The allegations in Plaintiffs’ complaints fall squarely within these considerations set forth in well-established Ohio law. *See* Master Compl., ¶¶ 152-158, 160-163, 177-190, 227-234.

While the American Society of Health-System Pharmacy (“ASHP”) Guidelines are not regulations, allegations related to them certainly may be considered and are relevant to establishing duty and the standard of care. *See Keeton v. Telemedia Co. of S. Ohio*, 98 Ohio App. 3d 405, 410, 648 N.E.2d 856, 859 (1994) (holding that a reasonable jury could conclude that defendant breached its duty to use due care by failing to follow industry guidelines.). Moreover, it is well-established that the allegations set forth by Plaintiffs alleging that the exercise of due care requires compliance with the ASHP Guidelines are to be taken in the light most favorable to Plaintiffs. *See* Master Compl., ¶¶ 191-193, 234(e), 249, 255(b). Furthermore, Plaintiffs’ experts, at a more appropriate, less premature time, will testify similarly.

Yet Plaintiffs allege more as it relates to duty, including allegations that the BKC

Defendants have a duty to warn, a well-established concept under Ohio law. “Assuredly, the physician-patient relationship is one of special trust and confidence in which the physician has a duty to reveal to the patient that which in his best interest he should know.” *Turner v. Children's Hosp., Inc.*, 76 Ohio App. 3d 541, 555, 602 N.E.2d 423, 431-32 (1991) (*citation omitted*); see also *Tracy v. Merrell Dow Pharm., Inc.*, 58 Ohio St. 3d 147, 150, 569 N.E.2d 875, 879 (1991) (“[t]he physician-patient relationship is a fiduciary one based on trust and confidence and obligating the physician to exercise good faith.”) (*citations omitted*). Indeed, “many courts have found physicians liable in malpractice for failure to communicate important information to patients” because “...patients must be told that which a reasonably prudent physician would disclose.” *Id.* Consequently, Plaintiffs have set forth sufficient allegations establishing BKC Defendants had a duty to fully inform them of many things, including, but not limited to: 1) the risks associated with non-FDA approved, preservative free MPA made by a compounding pharmacy, 2) that they were being injected with a non-FDA approved product, 3) the FDA approved available alternative, and 4) that they had not conducted any investigation into whether NECC was a reputable and safe supplier of injectable compounds. *See* Master Compl., ¶¶ 159-163, 179, 180, 189, 191-193, 199-204, 232-234(a), 234(g)-(l), 234(n), 301, 302.

BKC Defendants also ignore that Ohio’s Board of Pharmacy regulates prescribing doctors, placing the responsibility for proper prescribing of the drugs on both the pharmacy and the prescriber. *See* Ohio Admin. Code 4729-5-30. In part, this section requires that all prescriptions issued by a prescriber: (a) indicate the full name and residential address of the patient, (b) indicate the directions for use, and (c) identify the trade name or generic name of the drug(s) in a compounded prescription. *See* Ohio Admin. Code 4729-5-30(B)(1)-(14). Therefore,

Ohio regulations, similar to Massachusetts, place a duty on the prescriber to list the patient name and addresses and prohibit bulk ordering from compounding pharmacies.¹¹

As set forth above, Plaintiffs have sufficiently pled facts setting forth a duty owed by the BKC Defendants and, therefore, their Motion to Dismiss should be denied.

B. Plaintiffs Have Sufficiently Alleged Causation

The BKC Defendants contend that Plaintiffs' allegation that Dr. Batra/Dr. Katabay and BKC Pain were negligent in failing to provide patient-specific prescriptions and/or in providing "fake" patient lists in order to purchase medication from NECC fails to sufficiently allege causation, either factual or proximate, and that "the contamination would have occurred irrespective of whether patient-specific prescriptions were provided when purchasing the medication from NECC." Plaintiffs' allegations in the present matter do not assert any negligence claims against the BKC Defendants for the negligent *manufacture* of the contaminated MPA, but rather asserts, *inter alia*, negligence was committed in the performance of their medical services associated with obtaining and administering preservative free MPA from an unaccredited compounding pharmacy namely, NECC.

In making their unsubstantiated arguments, the BKC Defendants completely ignore over thirteen pages in the Master Complaint that allege numerous negligent acts and omissions by the BKC Defendants that caused Plaintiffs to be injected with contaminated drugs from NECC that resulted in their injuries. *See* Master Compl., ¶¶ 151-206, 226-242. Consequently, when viewing more than just the one selective allegation referenced by the BKC Defendants, it is

¹¹ Ohio Adm.Code 4731-21-02 has also codified rules for physicians treating intractable pain. In part, the standard identified requires, "formulating and documenting an individualized treatment plan specifying the medical justification of the treatment via the utilization of prescription drugs on a protracted basis or in combinations or amounts that may be inappropriate for treating other medical conditions." *Nucklos v. State Med. Bd. of Ohio*, No. 09AP-406, 2010-Ohio-2973, slip op. at 6 (Ohio Ct. Ap. June 29, 2010) (citing Ohio Adm. Code 4731-21-02(A)).

evident that Plaintiffs have sufficiently plead allegations to suggest both factual and proximate causation. Master Compl., ¶¶ 153, 174, 189, 199, 205-206, 207-210, 236- 242.

Plaintiffs' allege that multiple wrongful acts of the BKC Defendants caused their injuries. Indeed, the Plaintiffs allege that the BKC Defendants were negligent in purchasing non-FDA approved preservative-free drugs, to be injected directly into Plaintiffs' vulnerable central nervous systems, from an unaccredited compounding facility in bulk and under false names¹² and failing to perform any due diligence. *See* Master Compl. ¶¶ 154-155, 158-163, 165-166, 174-176, 180, 192, 199, 204, 234(a)-(q). Therefore, Plaintiffs have alleged that but for the BKC Defendants' negligent acts and omissions, Plaintiffs would not have been injected by the BKC Defendants with contaminated drugs resulting in injuries. *See* Master Compl., ¶¶ 153, 174, 189, 199, 205-206, 207-210, 237-242.

Additionally, contrary to what the BKC Defendants would like the Court to believe, courts in Ohio have held that concurrent or multiple causes can serve as the proximate cause for an injury and illness to a plaintiff. *See Czarney v. Porter*, 166 Ohio App.3d 830, 833, 853 N.E.2d 692, 693 (8th Dist. 2006) ("It is well accepted that two factors can combine to produce damage or illness, each being considered a proximate cause of the injury."); *see also State Farm Mut. Auto. Ins. Co. v. VanHoessen*, 114 Ohio App.3d 108, 112, 682 N.E.2d 1048, 1050 (1st Dist. 1996) ("An injury may have more than one proximate cause."). Therefore, the BKC Defendants cannot avoid liability simply by claiming that another party was also negligent and that negligence was the only proximate cause of the injuries. Plaintiffs have sufficiently set forth allegations of causation, warranting denial of Defendants' motion to dismiss.

¹² *See Exhibit 3* (Procedure logs produced by Defendants which show bulk orders of MPA with the names redacted).

C. Plaintiffs Have Sufficiently Alleged Gross Negligence.

As discussed above, Plaintiffs have set forth plausible allegations sufficient to support their contention that the BKC Defendants owed Plaintiffs a duty to exercise reasonable care. Given that the BKC Defendants owed Plaintiffs a duty, the Court must determine whether Plaintiffs provide sufficient factual allegations to support a gross negligence claim. The BKC Defendants argue that Plaintiffs' extensive allegations can't support a gross negligence claim as the term is defined under Ohio law. The Ohio Supreme Court defines "gross negligence" as the "failure to exercise any or very slight care[.]" and but also recognizes that "what may be mere ordinary negligence under one class of circumstances and conditions may become gross negligence under other conditions and circumstances." *Johnson v. State*, 66 Ohio St. 59, 67, 63 N.E. 607, 609 (1902).

In the instant case, the Master Complaint contains sufficient allegations that support the claim that the BKC Defendants failed to exercise any or even very slight care when they decided to place their bottom line before their patients' health and safety. Plaintiffs allege that the BKC Defendants decided to purchase non-FDA approved preservative-free MPA from an unaccredited compounding facility with a known history of contamination issues to inject directly into their patient's vulnerable spinal cords through an epidural injection without conducting any due diligence because it was cheaper than the FDA approved steroid. *See* Master Compl., ¶¶ 192, 198-99, 204. These circumstances and conditions may even be considered the type of class where ordinary negligence becomes gross negligence, as the Master Complaint specifically provides the following:

154. In many instances, the Clinic Related Defendants injected MPA directly into patients', including Plaintiffs', spinal canals so as to enter the central nervous system, bypassing many or all of the body's natural defensive mechanisms.

155. The Clinic Related Defendants knew, or should have known, that the central nervous system is a relatively closed system, making treatment options more difficult in the event of an adulterated invasion.

156. The Clinic Related Defendants knew, or should have known, that the MPA they purchased acts as an immune system-suppressing agent, thus weakening the patient's, including Plaintiffs', natural ability to fight off pathogens that could possibly be included in the injection.

See Master Compl. Due to the risks and complications associated with epidural steroid injections, even FDA approved steroids note on their label that the steroid is not recommended for injection into the epidural space near the spine because of reports of serious medical events, including death associated with administering steroids in that fashion.¹³ Additionally, the BKC Defendants billed at least two of the Plaintiffs for the more expensive FDA approved drug while administering the contaminated drug from NECC that they purchased in bulk, forty units at a time, without providing patient names or at the very least, the correct patient names. *See Exhibit 3*. Indeed, it's not feasible that the BKC Defendants had an even number of exactly 40 clients in need of MPA, month after month. The detailed averments above demonstrate that the Plaintiffs have provided sufficient factual allegations to support their claim for gross negligence at this time. To dismiss this claim when Plaintiffs have only just begun to receive production from Defendants, would be unwarranted and premature.

IV. Plaintiffs Set Forth Sufficient Allegations to State a Claim for Violations of Ohio's Consumer Sales Practices Act ("CSPA").

In an attempt to escape liability on this count, BKC Defendants completely disregard well-established Ohio law holding a hospital or health care facility under CSPA. In *Monroe v. Forum Health*, the court found that a "consumer transaction" as it is defined in O.R.C. 1345.0

¹³ David Armstrong, *Bristol-Myers Warning Ignored on Steroid Shots Tied to Deaths*, Bloomberg, January 25, 2012, <http://www.bloomberg.com/news/2012-01-25/bristol-myers-warning-ignored-on-steroid-shots-tied-to-deaths.html>.

can include hospitals. *See Monroe v. Forum Health*, No. 2012-T-0206, 2012-Ohio-6133, slip op. at 10 (Ohio Ct. App. Dec. 24, 2012). The court wrote, “[v]arious courts have held that CSPA claims can be raised against hospitals or medical service providers, since they are not specifically exempted by the statute.” *Id.*; *see also Elder v. Fischer*, 129 Ohio App.3d 209, 215, 717 N.E.2d 730, 734 (1st Dist.1998) (“...we conclude that had the legislature wanted to exclude from the purview of the CSPA residential-care facilities or any other businesses or professions, it only needed to have said so.”); *Summa Health Sys. v. Vinigre*, 140 Ohio App. 3d 780, 795-96, 749 N.E.2d 344, 356 (2000) (holding “a transaction between a service provider such as a hospital and the consumer is not clearly exempted” from the CSPA.). Moreover, “Ohio’s CSPA, like New Jersey’s consumer-protection statute, is a remedial statute and, thus, should be broadly construed to effectuate its purpose of protecting consumers.” *Elder*, 129 Ohio App.3d at 219.

Plaintiffs have sufficiently stated allegations of violations of Ohio Consumer Sales Practices Act per O.R.C. s 1345.01 plausible to entitle them to relief. *See* Master Compl., Count IV. BKC Defendants made representations to Plaintiffs that they were getting a safe and effective steroid. Furthermore, BKC Defendants actually billed Plaintiffs for the FDA approved DepoMedrol, rather than the non-FDA approved preservative-free MPA, which they actually received. *See Exhibit 4*. Defendant BKC Pain Specialists, LLC, the health care facility employing the physicians, fraudulently and intentionally billed Plaintiffs for an FDA approved drug, rather than the NECC contaminated drug they were actually getting. Consequently, Plaintiffs have sufficiently stated a claim against the healthcare facility, Defendant BKC Pain Specialists, LLC, for a violation of the CSPA.¹⁴ Moreover, all BKC Defendants, including the

¹⁴ While *Walsh v. Erie Cnty. Dep't of Job & Family Servs.*, makes a distinction between a “hospital” as in *Summa* and a “group of doctors,” the court denies defendants partial motion for summary judgment on this issue because it is not an issue that has been decided in the Northern District of Ohio. 240 F. Supp. 2d 731, 767-68 (N.D. Ohio 2003). As a result, since BKC Defendants are attempting to dismiss the claim under 12(b)(6), a much lower burden

physicians, may be held liable under M.G.L. c. 93A. *See* M.G.L. c. 93A, §§ 1, 9. For these reasons, Plaintiffs request this Court deny BKC Defendants' motion to dismiss the violation of CSPA cause of action.

V. Plaintiffs Have Sufficiently Pled a Cause of Action Against BKC Defendants for Battery.

Pleading battery is simple: "A physician who treats a patient without consent commits a battery." *Estate of Leach v. Shapiro*, 13 Ohio App. 3d 393, 395, 469 N.E.2d 1047, 1051-52 (1984) (citing *Lacey v. Laird* (1956), 166 Ohio St. 12, 25, 139 N.E.2d 25, 34 (1956)). BKC Defendants incorrectly claim that Plaintiffs consented to the injection and therefore cannot prove battery based on allegations that they signed a consent form. As an initial matter, the premise for BKC Defendants' entire argument is left unsubstantiated, as they fail to attach any alleged consent forms executed by Plaintiffs. However, even if Plaintiffs did execute informed consent forms, BKC Defendants conveniently disregard that any consent must be "informed." It is well-established that "the patient's consent must be informed consent. There is no legal defense to battery if the patient's consent is given without sufficient knowledge and understanding of the touching." *Id.* at 395 (*citation omitted*). BKC Defendants completely disregard Plaintiffs' allegations that any alleged consent was not informed given that any alleged consent was without sufficient knowledge and understanding of the nature of the injections.

As plaintiffs sufficiently pled in Counts VII and XIII of the Master Complaint, "Plaintiffs were unaware of the substantial health and safety risk inherent in the use of NECC Contaminated Drugs and did not consent to the injection of contaminated drugs into their bodies." *See* Master Complaint, ¶ 297. Plaintiffs also pled that the BKC Defendants failed to properly and fully

than a motion for summary judgment under Fed. Civ. P. Rule 56, BKC Defendants motion to dismiss should be denied and this question should be left to the trier of fact. *See Id.*

advise Plaintiffs, among other things, that (a) they were getting the MPA from the NECC, (b) the NECC was not accredited by any valid accrediting organization, (c) the MPA was not FDA approved, and/or (d) the material risks associated with compounding preservative free steroid preparation which had not been FDA approved. *See e.g.* Short Form Compl. Dkt. No. 1:13-cv-12658-RWZ, Doc. No. 23, filed December 19, 2013. In the same section, Plaintiffs allege a reasonable person, including Plaintiffs, would have decided *against* undergoing the ESI procedure had the “...full material facts and risks, including the forgoing, been disclosed and explained prior to the procedure.” *Id.* Plaintiffs, therefore, have sufficiently pled a claim for lack of informed consent, and consequently, battery.

Furthermore, informed consent is a question of fact which should be determined by the trier of fact after expert testimony is given. *See Wells v. Van Nort* 100 Ohio St. at 103. (“The existence of consent, either express or implied, is a question of fact.”). Therefore, BKC Defendants’ motion to dismiss the civil battery claim is not proper at this point and entirely premature. Dismissal should be denied.

VI. Plaintiffs Properly Allege Violations of Ohio Products Liability Act (“OPLA”).

A. Plaintiffs’ Short Form Complaints Properly Allege a Violation of OPLA through Incorporation of the Master Complaint and Amended Long Form Complaints.

In seeking dismissal of Plaintiffs’ OPLA claim, BKC Defendants ignore entirely the usual MDL process and allegations in the Master Complaint, setting forth “This master complaint is filed for administrative purposes only. It does not replace or supersede the complaints associated with existing civil actions.” Master Compl., ¶ 9. In the normal course, master complaints are adopted by short form complaints, and long form complaints are drafted and filed when a case is selected for bellwether trial. This is the efficient way of moving cases forward in an MDL involving the potential application of laws of dozens of states, and in fact,

the number of motions to dismiss filed in the MDL at this stage is unprecedented. The Master Complaint sets forth allegations meant to apply across fifty states, certainly it would have been unduly burdensome and unworkable for Plaintiffs to break down product liability law in every state involved in this tragedy.

Nonetheless, Plaintiffs sufficiently plead facts alleging a violation of OPLA in the Master Complaint, even if the statute was not specifically identified. Moreover, Plaintiffs incorporated all facts and allegations set forth in the Master Complaint and previously filed long form complaints into their short form complaints. B. Cooper Short Form Compl. Dkt. No. 1:13-cv-12658-RWZ, Doc. No. 23, filed December 19, 2013; P. Cooper Short Form Compl. Dkt. No. 1:13-cv-12659- RWZ, Doc. No. 23, filed December 19, 2013; and D. Montee Short Form Compl. Dkt. No. 1:13-cv-12657- RWZ, Doc. No. 27, filed December 19, 2013. BKC Defendants disregard all the allegations actually made against Defendants in the Master Complaint, even if they were not specifically directed at the Ohio Products Liability Act. BKC Defendants also fail to cite any case law to support their contention. Recognizing that Plaintiffs adopted Count IX, which sets forth allegations of violations of product liability law in Tennessee, BKC Defendants ignore entirely that the Ohio law is the same, i.e. that the BKC Defendants can be held liable if the Plaintiffs are “unable to enforce a judgment against a manufacturer of that product due to insolvency of the manufacturer. See O.R.C. § 2307.78(B)(2).” *See* BKC Brief p. 16; *see also* Master Complaint, Count IX.

Further, dismissal is not the appropriate remedy, rather Plaintiffs should have an opportunity to amend these claims to specifically name the OPLA. *See EEOC v. Ohio Edison Co.*, 7 F.3d 541, 546 (6th Cir.1993) (“where a more carefully drafted complaint might state a claim, a plaintiff must be given at least one chance to amend the complaint before the district

court dismisses the action with prejudice.”) (*quoting Bank v. Pitt*, 928 F.2d 1108, 1112 (11th Cir.1991)); *see also Fisher v. Roberts*, 125 F.3d 974, 977-78 (6th Cir. 1997) (“We have recognized that it is necessary to permit the liberal amendment of complaints in order to adhere to ‘the principle that cases should be tried on their merits rather than on the technicalities of pleading.’”) (*quoting Janikowski v. Bendix Corp.*, 823 F.2d 945, 950 (6th Cir. 1987). For the reasons set forth above, BKC Defendants’ motion should be denied.

B. B KC Defendants can be Liable as “suppliers” Under the OPLA for all Causes of Action.

Contrary to what the BKC Defendants would like the Court to believe, it is well-established under Ohio law, that hospitals are suppliers under the OPLA. In *Saylor v. Providence Hosp.*, a hospital argued that it was not a “supplier” or “seller” under the OPLA of screws and plates that were negligently manufactured and inserted into plaintiff’s skull. 113 Ohio App. 3d at 5-8. The hospital argued they could only be considered an “intermediary supplier,” and therefore were not liable. *Id.* The court disagreed and denied dismissal. *Id.* The *Saylor* court cited *Anderson v. Olmsted Util. Equip., Inc.*, 60 Ohio St.3d 124, 127-129, 573 N.E.2d 626, 629-630 (1991), stating, “the Supreme Court of Ohio declined to limit supplier liability to an actual sale in the traditional sense, holding that the only relevant question was whether the “seller” facilitated placing the product into the stream of commerce.” *Id.* at 1965. Clearly, as alleged, by purchasing the contaminated MPA from NECC and selling it to Plaintiffs and billing them and their insurers, BKC Defendants have facilitated placing the MPA into the stream of commerce. *See* Master Complaint, ¶¶ 319, 320, 333. Further, the court wrote, “Ohio’s codification of products liability law is a continuum which follows the product. The consumer, in this case the patient, is at the least culpable end of the chain,” just like the Plaintiffs here. *Id.* Therefore, the healthcare facility, and likely the physicians, are liable for facilitating in the placement of

NECC's contaminated MPA into the stream of commerce, injecting it into Plaintiffs and billing them and their insurers for it.

As BKC Defendants appropriately concede, suppliers can be held liable for the actions of the manufacturer if the claimant will not be able to recover because of insolvency on the part of the manufacturer, as it is in this case given that NECC is now insolvent. *See* O.R.C. § 2307.78(B)(2). For this reason alone, the OPLA count cannot be dismissed. Moreover, suppliers can also be independently liable if: (a) the supplier was negligent and the negligence proximately caused the claimant harm; or (b) the product in question, when it left the supplier's control, did not conform to a representation made by the supplier and that representation and failure to conform proximately caused the claimant harm. *See* O.R.C. § 2307.78(A). As set forth herein the sections related to negligence and causation, the BKC Defendants were negligent and their negligence caused Plaintiffs' injuries making them liable under OPLA. Moreover, the MPA did not conform with representations made by the BKC Defendants because it was not a safe product. Dismissing the above claims would be inappropriate given that all facts should be taken in the light most favorable to Plaintiffs and that they sufficiently plead allegations plausible to an entitlement of relief. Plaintiffs respectfully request this Court deny BKC Defendants' Motion to Dismiss violations of OPLA.

VII. Plaintiffs' Complaints Sufficiently Set Forth a Failure to Warn Claim

A. Plaintiffs' Failure to Warn Claims are Not Abrogated by the OPLA

In claiming that Plaintiffs' failure to warn claims are abrogated by the OPLA, BKC Defendants entirely ignore many allegations regarding their failure to warn that relate not to just the defective product, but also their failure to warn of several other things unrelated to the product, including, for example, the vulnerability of the central nervous system, their

involvement in bulk purchasing, the existence of safer alternatives, and the use of an unaccredited compounding pharmacy as opposed to an FDA regulated manufacturer for creation of the product. *See* Master Compl., ¶¶ 154-156, 158, 161-163, 183, 232-234. Moreover, many of Plaintiffs’ other allegations of “failure to warn” at common law are based on a “lack of informed consent” due to the conduct of Defendants. *See* Master Compl., ¶302. In Ohio, courts have equated a “failure to warn” claim against a doctor to a “lack of informed consent claim.” *See Saxe v. United States*, 577 F. Supp. 135, 146 (N.D. Ohio 1983) aff’d, 751 F.2d 386 (6th Cir. 1984). These allegations obviously relate to Defendants’ conduct and their malpractice and not the product and therefore, are not abrogated.

Notably, BKC Defendants cannot have it both ways – either Plaintiffs have a valid OPLA claim or they do not. And if not, the common law failure to warn claim cannot be subsumed by the OPLA and it stands on its own unaffected by it. Moreover, “[t]he supplier may be held independently liable for misrepresentations or negligence. This includes failure to warn or inadequate warnings.” *Saylor*, 113 Ohio App. 3d at 5-8. Nonetheless, Plaintiffs have pled sufficient facts related to the BKC Defendants’ failure to warn, not only about the contaminated MPA, but other critical information not product based. Dismissal. Therefore, dismissal should be denied.

B. Plaintiffs’ Complaints which Incorporate the Master and Long Forms, Adequately Allege All Elements of a Common Law Failure to Warn Claim

BKC Defendants ignore many claims in the Master Complaint, that was adopted and incorporated by reference in Plaintiffs’ Short Form Complaints, which establish that Plaintiffs sufficiently plead all of the elements of a failure to warn claim. Each and every allegation BKC Defendants claim are missing are actually in the Master Complaint, as set forth in the paragraphs below in bold in Count VIII – Failure to Warn:

301. **The Clinic Related Defendants failed to inform their patients, including Plaintiffs, that they were being administered an unsafe, unreasonably dangerous drug compounded by NECC rather than a high quality drug produced by an FDA regulated manufacturer.**

302. Many, if not all, of the Clinic Related Defendants prepared a Consent for Treatment Form. The form, which was presented to Plaintiffs by the Clinic Related Defendants, and which Plaintiffs read and relied upon when agreeing to accept treatment, failed to inform the Plaintiffs of the risks and benefits of the procedures before it was performed. When presenting the form to Plaintiffs, the Clinic Related Defendants knew that nobody on its behalf would be informing Plaintiffs of the inferior and unreasonably dangerous nature of the NECC drug that would be administered to Plaintiffs. Clinic Related Defendants knew that **if Plaintiffs were informed of the true nature of the NECC drugs, Plaintiffs would decline treatment with NECC drugs, threatening the Healthcare Providers' profits.**

303. As a proximate result of the Clinic Related Defendants' wrongful conduct, Plaintiffs suffered grievous bodily injury and/or death, have required extensive medical treatment, have incurred and in the future will incur substantial medical bills and have suffered and will in the future suffer inconvenience and severe mental anguish.

See Master Compl. ¶¶ 301-303.

Thus, the detailed averments above demonstrate that the Master Complaint provides sufficient factual allegations to support Plaintiffs' claims for failure to warn/lack of informed consent in Count VIII. Moreover, whether BKC Defendant's appropriately warned Plaintiffs is a question of fact. *Wells v. Van Nort* (1919), 100 Ohio St. 101, 125 N.E. 910; *see also Guth v. Huron Rd. Hosp.*, 43 Ohio App. 3d 83, 86, 539 N.E.2d 670, 673-74 (1987) ("Without recourse to expert testimony...these issues are not appropriately resolved through the granting of appellees' motions for summary judgment."). Dismissal of this claim is improper and premature.

VIII. Plaintiffs Have Sufficiently Pled a Cause of Action for Agency Under Ohio Law.

Plaintiffs set forth several allegations establishing a right to entitlement of relief under an agency claim. BKC Defendants' conclusory statements such as "the purchase of medication by a doctor's office from a pharmacy does not create an agency relationship," is not supported by law and not for the BKC Defendants to decide. BKC Defendants argument that Plaintiffs fail to

establish the “right of control,” ignores that the Plaintiffs need not prove anything at this stage and disregards an entire count in the Master Complaint, among other paragraphs, which establish the existence of the agency relationship. Plaintiffs specifically allege “[t]he Clinic Related Defendants controlled the procurement of the drugs from NECC to be sold and administered to their patients, including the Plaintiffs.” Master Compl., ¶ 335. In *Griffith v. Rutledge*, the court analyzed the element of “control” in an agency relationship and so stated, “...we are of the opinion that the right of control rather than the actual exercise of the right determines agency and responsibility.” 110 Ohio App. 301, 304-07, 169 N.E.2d 464, 466-68 (1959). Plaintiffs specifically allege “The Clinic Related Defendants controlled the procurement of the drugs from NECC to be sold and administered to their patients, including to Patients.”

Additionally, Count X – Agency of Plaintiffs’ Master Complaint, alleges the following:

329. All allegations above are incorporated herein by reference.

330. At all times relevant herein, NECC was acting as an agent of the Clinic Related Defendants in compounding drugs to be administered to the Plaintiffs by the Clinic Related Defendants.

331. A consensual fiduciary relationship arose when the Clinic Related Defendants contracted with NECC to procure compounded drugs from NECC for their patients, including Plaintiffs.

332. The Clinic Related Defendants manifested assent for NECC to act as their agent, and on their behalf, when the Clinic Related Defendants contracted with NECC to procure compounded drugs from NECC to administer to their patients, including Plaintiffs.

333. NECC consented to act as the Clinic Related Defendants’ agent, and in the Clinic Related Defendants’ interest, when compounding, selling and delivering its compounded drugs to the Clinic Related Defendants, to be sold and administered to the Clinic Related Defendants’ patients, including the Plaintiffs.

334. At all times relevant herein, NECC acted within the scope of its agency with the Clinic Related Defendants. As set forth herein, NECC acted negligently and or exhibited gross negligence in the compounding of NECC contaminated drugs.

335. The Clinic Related Defendants controlled the procurement of the drugs from NECC to be sold and administered to their patients, including the Plaintiffs.

336. As a result, the Clinic Related Defendants are responsible for the negligence, gross negligence and wrongful conduct of NECC in compounding

the contaminated drugs administered to Plaintiffs.

(See Master Compl., ¶¶ 329-336.)

Moreover, none of the cases cited by the BKC Defendants were decided pursuant to a Motion to Dismiss standard. To the contrary, the decisions were made following the development of an evidentiary record through discovery.¹⁵ Here, Plaintiffs have not been provided an opportunity to develop an evidentiary record through discovery. Thus, viewing any reasonable inferences from the factual allegations contained in the Plaintiffs' Master Complaint in the light most favorable to Plaintiffs, Plaintiffs have set forth a claim of agency against the BKC Defendants sufficient to survive dismissal.

IX. Plaintiffs Have Sufficiently Pled a Claim for Civil Conspiracy under Ohio Law.

In evaluating a Rule 12(b)(6) motion to dismiss for failure to state a claim, “[t]he Court is without authority to dismiss the claims unless it can be demonstrated beyond a doubt that the plaintiff can prove no set of facts that would entitle it to relief.” *Ziegler v. Findlay Indus., Inc.*, 380 F. Supp. 2d 909, 911 (N.D. Ohio 2005). In Ohio, a civil conspiracy claim has four elements, “(1) a malicious combination; (2) two or more persons; (3) injury to person or property; and (4) existence of an unlawful act independent from the actual conspiracy.” *Universal Coach, Inc. v. New York City Transit Auth., Inc.*, 90 Ohio App.3d 284, 629 N.E.2d 28, 33 (1993). BKC Defendants dispute whether Plaintiffs have sufficiently pled “malicious combination” and the

¹⁵ See *Evans v. Ohio State Univ.*, 112 Ohio App. 3d 724, 740, 680 N.E.2d 161, 171 (1996) (Judgment in favor of Defendants); *Mermer v. Med. Correspondence Servs.*, 115 Ohio App. 3d 717, 721, 686 N.E.2d 296, 299 (1996) (Court of Appeals reversed lower court's decision in favor of Plaintiffs); *Hanson v. Kynast*, 24 Ohio St. 3d 171, 494 N.E.2d 1091 (1986) (Motion for summary judgment was properly granted as the element of control was not present); *Adlaka v. Valley Elec. Consol., Inc.*, No. 2007-T-0071, 2008 WL 943488 (Ohio Ct. App. April 4, 2008) (Court affirmed ruling in favor of granting of summary judgment. The court found that the important element in determining the existence of an agency relationship is the existence of control over the conduct and activities of the alleged agent. *Haluka v. Baker*, 66 Ohio App. 308, 34 N.E.2d 68 (1941) (Court affirmed Judgment for Defendant); *Nee v. State Indus., Inc.*, 3 N.E.3d 1290, 2013-Ohio-4794 (Ohio Ct. App. Oct. 31, 2013) (Summary Judgment was denied because a genuine issues of fact existed as to whether there was an agency).

existence of an unlawful act independent from the actual conspiracy.

Contrary to what the BKC Defendants would like the Court to believe, a review of the Master Complaint reveals that Plaintiffs have sufficiently pled a conspiracy count:

338. The **Clinic Related Defendants acted in concert with NECC, its agents and employees, to accomplish the unlawful purpose of circumventing Massachusetts Board of Pharmacy patient safety requirements. Those Defendants accomplished that unlawful purpose via the unlawful means of using bogus patient lists** to accompany orders of MPA.

339. The Clinic Related Defendants were involved in a conspiracy in connection with NECC's scheme to **wrongfully mislead the Massachusetts Pharmacy Board** (the "Board") related to NECC's attempted compliance with the Board's rules and regulations and the Clinic Related Defendants willfully, intentionally, and/or recklessly participated in the conspiracy. The conspiracy resulted in NECC being able to maintain compliance with the Board's Rules and Regulations when in fact it was not in such compliance. The Board's **rules and regulations are in place to ensure patient safety, and a natural and anticipated outcome from intentional and willful violation of the Board's rules and regulations would be the compromise of patient health and safety.** Such Board rules include, but are not limited to, 105 CMR § 700.12.

340. The conspiracy principally involved NECC's request that the Clinic Related Defendants provide patient names for patients the Clinic Related Defendants intended to provide with MPA or other pharmaceuticals. The Clinic Related Defendants, however, could not provide such patient lists and NECC requested the Clinic Related Defendants submit any list of names to be provided to the Board. The Clinic Related Defendants then complied with the request by submitting a list of patients, regardless of whether those patients actually were or would be prescribed MPA or other NECC drugs.

341. **The Clinic Related Defendants knew or reasonably should have known that patient specific names were required by virtue of the fact that NECC's standard order form for MPA and other drugs requested patient specific information. Instead of filling out these standard forms properly, the Clinic Related Defendants ordered NECC pharmaceuticals in bulk and thereafter submitted list of patient names, regardless of whether those patients received the ordered pharmaceuticals.**

342. **The Clinic Related Defendants were aware of NECC's intent to use such patient lists in order to subvert Massachusetts Board of Pharmacy requirements.**

(See Master Compl., ¶¶ 338-342.) (Emphasis Added.)

Plaintiffs sufficiently allege "malicious combination" by setting forth allegations that the BKC Defendants acted purposely or knowingly to the injury of another. *See Williams v. Aetna Fin. Co.*, 83 Ohio St. 3d 464, 475, 700 N.E.2d 859, 868 (1998). Indeed, "[the] element of 'malicious combination to injure' does not require a showing of an express agreement between

defendants, but only a common understanding or design, even if tacit, to commit an unlawful act.” *Gosden v. Louis*, 116 Ohio App. 3d 195, 219-22 (1996) (*citation omitted*). The Master Complaint specifically alleges that BKC Defendants knew or should have known they were required, under Massachusetts law, to submit patient lists for all the prescriptions they were ordering and that they acted in concert with NECC to circumvent the law, resulting in injury to Plaintiffs. *See* Master Compl., ¶¶ 338, 339, 341, 342. Moreover, “[a] plaintiff need not demonstrate an explicit agreement but only an understanding or common design between the parties to commit an improper act.” *Gosden v. Louis*, 116 Ohio App.3d at 219-22. Plaintiffs specifically allege that BKC Defendants “knowingly” acted and that they “acted in concert” with NECC, satisfying the “malicious combination” element of the claim.

Defendants ignore both the detailed allegations of an unlawful act set forth above when unlawfully buying in bulk and submitting false patient names. Moreover, Ohio case law clearly states that Plaintiffs need not prove the unlawful act was committed by each of the alleged conspirators; instead, Plaintiffs must only allege one member of the conspiracy committed the unlawful act. *See Hale v. Enerco Grp., Inc.*, 1:10 CV 00867-DAP, 2011 WL 49545 (N.D. Ohio Jan. 5, 2011). Regardless of BKC’s actions, is undisputed that NECC engaged in unlawful conduct. Even at trial, never mind the much lower threshold of a pleading, parties prove conspiracy through circumstantial evidence. *See re Nat’l Century Fin. Enterprises, Inc., Inv. Litig.*, 604 F. Supp. 2d 1128, 1154 (S.D. Ohio 2009) (*citing Aetna*, 219 F.3d at 538) (stating that the existence of a tacit understanding is often “provable only through circumstantial evidence”). Indeed, “[r]arely in a conspiracy case will there be direct evidence of an express agreement among all the conspirators to conspire, ... circumstantial evidence may provide adequate proof of conspiracy.” *Weberg v. Franks*, 229 F.3d 514, 528 (6th Cir. 2000) (*citation omitted*).

Lastly, Plaintiffs discussed above, they have not been provided an opportunity to develop an evidentiary record through discovery and what the BKC Defendants have produced, up until this point, has been grossly insufficient. Indeed, in *LeFort v. Century 21-Midland Realty & Co.*, the court determined that “[t]he ultimate fact of conspiracy is solely a question for the jury, unless the court can say, as a matter of law, that there is no proof tending to establish a conspiracy.” 32 Ohio St.3d 121, 126, 512 N.E.2d 640, 645 (1987) (citations omitted). Thus, under the applicable Ohio law, and viewing any reasonable inferences from the factual allegations contained in the Master Complaint in the light most favorable to Plaintiffs, Plaintiffs have set forth a sufficient claim of civil conspiracy against the BKC Defendants. Dismissal of this civil conspiracy claim is premature and improper.

X. Allegations Against Defendants are Sufficient to Sustain a Claim For Punitive Damages in Ohio.

Plaintiffs’ allegations sufficiently state a claim for punitive damages. Plaintiffs must simply plead the actions go beyond mere negligence so as to rise to the level as “a conscious disregard for the rights and safety of other persons that has a great probability of causing substantial harm.” *See Preston v. Murty*, 32 Ohio St.3d 334, 335, 512 N.E.2d 1174, 1175-1176 (1987). Despite the BKC Defendants’ contentions, Plaintiffs have more than sufficiently pled BKC Defendants’ actions represent a conscious disregard for the rights and safety of other persons that has a great probability of causing and did cause substantial harm. In fact, with respect to Defendants’ conduct, the Master Complaint states in pertinent part:

237. The foregoing acts and omissions by the Clinic Related Defendants went beyond mere thoughtlessness, inadvertence or error of judgment.

238. The actions of the Clinic Related Defendants did not meet even the most minimal diligence to ensure that they were not injecting contaminated, adulterated, tainted, and unreasonably dangerous drugs directly into the bodies of their patients, including Plaintiffs.

239. The acts and omissions of the Clinic Related Defendants constituted such utter disregard for the rights of others, and such utter disregard for prudence, that they amount to complete neglect of the safety of patients, including Plaintiffs.

* * *

249. Clinic Related Defendants ***willfully and knowingly*** failed to abide by regulations, laws and guidelines set forth to protect consumer safety, constituting a violation of the consumer protection statutes set forth herein.

250. Clinic Related Defendants' ***willful and knowing*** withholding of important safety information and critical product information constitutes a violation of various state consumer protection statutes set forth herein.

251. Clinic Related Defendants ***actively, knowingly, and deceptively*** concealed the product's dangerous properties and life-threatening risks of which they knew or should have know [sic]. This conduct evidences bad faith and unfair and deceptive practices.

(See Master Compl., ¶¶ 237-251)

Furthermore, a claim for punitive damages should be evaluated at the end of the discovery period when all information discoverable has been disclosed to both parties. Because Plaintiffs have alleged that Defendants' actions were "willful" and "knowing," and because such conduct went beyond mere assertions of negligence so as to create a "conscious disregard for safety," Plaintiffs have adequately and sufficiently stated a claim for punitive damages in Ohio. Furthermore, dismissal on this action would be premature as Plaintiffs have not had the benefit of discovery to fully develop their cause of action. In the alternative, should this Court find the pleadings somehow deficient, Plaintiffs should be granted leave to amend their complaints.

XI. Plaintiffs Should be Provided the Opportunity to Amend their Master Complaint.

Even assuming, *arguendo*, that this Court concludes that the factual allegations against the BKC Defendants were inadequately pleaded, the Federal Rules of Civil Procedure direct courts to freely provide the opportunity to amend a complaint: "[t]he court should freely give leave when justice so requires." Fed. R. Civ. P. 15(a). If a complaint is subject to dismissal per Fed. R. Civ. P. 12(b)(6), leave should be given to amend unless doing so would be futile or cause undue delay. *See Steir v. Girl Scouts of the USA*, 383 F.3d 7, 12 (1st Cir. 2004). If leave to

amend is sought before discovery, “amendment is not deemed futile as long as the proposed amended complaint sets forth a general scenario which, if proven, would entitle the plaintiff to relief against the defendant on some cognizable theory.” *Hatch v. Dep’t for Children, Youth & Their Families*, 274 F.3d 12, 19 (1st Cir. 2001). The complaints in the cases at bar are not tainted with either futility or undue delay and Plaintiffs ask that this Honorable Court provide an opportunity to amend their complaints should the Court deem it necessary.

CONCLUSION

Wherefore, for the foregoing reasons, Plaintiffs respectfully request that this Court deny BKC Defendants’ Motion to Dismiss in its entirety. In the alternative, should this Court determine that Plaintiffs’ allegations are deficient, Plaintiffs’ respectfully request the opportunity to amend their complaints to address any shortcomings.

Date: April 4, 2014

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I, Kimberly A. Dougherty, hereby certify that I caused a copy of the above *Plaintiffs' Steering Committee's Memorandum of Law in Opposition to BKC Defendants' Motion to Dismiss Pursuant to F.R.C.P. 12(b)(6)* pursuant to Local Rule 7.1(b)(4) to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Dated: **April 4, 2014**

/s/ Kimberly A. Dougherty
Kimberly A. Dougherty, Esq.